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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,239	02/05/2007	Avidor Shulman	7056-X08-022	9066

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EXAMINER	
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ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,239	SHULMAN ET AL.	
	Examiner	Art Unit	
	MELISSA S. MERCIER	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 May 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-30,32-39 and 41* is/are pending in the application.

4a) Of the above claim(s) *13-24,26-30 and 35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25, 32-34, 36-39 and 41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

Receipt of Applicants Remarks and Amended Claims filed on May 5, 2010 is acknowledged. Claims 13-30, 32-39, and 41 are pending in this application. Claims 13-24, 26-30, and 35 remain withdrawn from consideration. Therefore, claims 25, 32-34, 36-39 and 41 are under prosecution in this application.

Withdrawn Rejections

Claim Rejections - 35 USC § 112

The rejection of claims 25, 31-34, and 36-40under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been withdrawn in view of Applicants amendment to claim 25 to remove the phase “does not inhibit calcium absorption.

Maintained Rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25, 32, 34, and 36-37 are rejected under 35 U.S.C. 102(b) as being anticipated by FoodIngredientsFirst article, Enzymotec launches InFat-perfect fat for infant formulas, available online April 7, 2003).

The article discloses the use of InFat, which the specification discloses is the lipid component of the instant invention. The article further discloses that incorporating InFat into infant formulas will increase a baby's energy and calcium intake.

InFat therefore anticipates the method of the instant claims.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive. Applicant argues:

***Infant formula has been excluded and therefore, does not anticipate the method of using the composition.**

The Examiner respectfully disagrees. A composition's functionality can not be separated from its components. Therefore, while the intended use of the composition may be as an infant formula, there is nothing of record to indicate that the future intended use of the composition has provided any structural difference to the composition and therefore it would be expected to function in an identical manner whether it was called an infant formula or an adult nutritional supplement.

Claims 25, 32, 34, and 36-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Spurgeon et al, hereinafter referred to as Spurgeon, (An investigation of

the general, reproductive and postnatal developmental toxicity of Betapol, a human milk fat equivalent; available online August 2, 2003).

Spurgeon discloses the use of Betapol in infant foods as well as foods in general (abstract). Applicant has indicated that Betapol is a commercially available product meeting the structural requirements of the instantly claimed lipid (pages 10 and 15 of the instant specification).

Spurgeon discloses the use of Betapol provides enhanced fat absorption and calcium retention.

Regarding claims 34 and 36, the claims recite functional properties of the lipid component. Since Spurgeon discloses the same lipid, it would necessarily also perform the same functional properties.

Betapol therefore anticipated the method of the instant claims.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive. Applicant argues:

Betapol provides enhanced calcium retention and not calcium absorption.

It is unclear to the Examiner what Applicants argument actually is. It is unclear if Applicant things that retaining calcium from an infant formula is distinct or different from absorbing the calcium. It is the positon of the Examiner that they are equivalents. It is unclear what other type of retention would be applicable.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 25, 31-34, and 36-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spurgeon et al, hereinafter referred to as Spurgeon, (An investigation of the general, reproductive and postnatal developmental toxicity of Betapol, a human milk fat equivalent; available online August 2, 2003) in view of Kennedy et al. (Double blind, randomized trial of a synthetic triacylglyercol in formula fed term infants: effects on stool biochemistry, stool characteristics, and bone mineralization).

The teachings of Spurgeon has been discussed above and applied in the same manner.

Spurgeon does not disclose what additional components are contained within the food product. It is noted that Applicant has amended the claims to recite a child or adult, however, it is the position of the Examiner that a child would encompass an infant. Applicant has not defined an exact age range to define each grouping separately to distinguish them.

Regarding claims 34 and 36, the claims recite functional properties of the lipid component. Since Spurgeon discloses the same lipid, it would necessarily also perform the same functional properties.

Regarding claims 38-40, while Spurgeon does not specifically disclose the incorporation of Betapol into pastries, breads, and infant food which is not formula, it would have been obvious to the skilled artisan to incorporate it into said articles based on the teachings of Spurgeon as acceptable for use in food articles in general. It would have been obvious to a skilled artisan to try to incorporate it into food articles in order to obtain the same beneficial properties which are seen in the infant formula.

Kennedy discloses an infant formula comprising triacylglyercols with high sn-2 palmitate on the glyercol backbone and calcium, among other vitamins, was administered to term infants and showed an increase in calcium absorption and greater skeletal mineral deposition. The formula further comprised proteins, carbohydrates, and vitamins which are considered to be edible additives, thereby meeting the limitation of claim 31.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the lipid component of Spurgeon in the infant formula of Kennedy since Spurgeon discloses the Betapol provides enhanced fat absorption and calcium retention.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive.

Applicant argues:

Claims 25, 31-34, 36-37, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over FoodIngredientsFirst article, Enzymotec launches InFat-perfect fat for

infant formulas, available online April 7, 2003) in view of Kennedy et al. (Double blind, randomized trial of a synthetic triacylglyercol in formula fed term infants: effects on stool biochemistry, stool characteristics, and bone mineralization).

The FoodIngredientFirst article has been discussed above and applied in the same manner.

The FoodIngredientFirst article does not disclose what additional components are contained within the food product. It is noted that Applicant has amended the claims to recite a child or adult, however, it is the position of the Examiner that a child would encompass an infant. Applicant has not defined an exact age range to define each grouping separately to distinguish them.

Kennedy discloses an infant formula comprising triacylglyercols with high sn-2 palmitate on the glyercol backbone and calcium, among other vitamins, was administered to term infants and showed an increase in calcium absorption and greater skeletal mineral deposition. The formula further comprised proteins, carbohydrates, and vitamins which are considered to be edible additives, thereby meeting the limitation of claim 31.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the lipid component InFat in the infant formula of Kennedy since it is disclosed that increase a babies energy and calcium intake.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive.

Applicant has argued the two rejections under 35 USC 103 together; therefore, the Examiner will address the remarks together.

***Infant formula has been excluded and therefore, does not anticipate the method of using the composition.**

The Examiner again respectfully disagrees. As discussed above, a composition's functionality can not be separated from its components. Therefore, while the intended use of the composition may be as an infant formula, there is nothing of record to indicate that the future intended use of the composition has provided any structural difference to the composition and therefore it would be expected to function in an identical manner whether it was called an infant formula or an adult nutritional supplement.

Newly Applied Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25, 32-34, 36-39 and 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

application was filed, had possession of the claimed invention. Applicant has amended the claims to recite a non-infant child; however, the specification does not support this amendment. Particularly, Applicants attention is directed to page 7 of the instant specification which discloses the dietary supplementation of minerals is need for infants and young children, as well as adults, especially women over 45". **This is a New Matter Rejection.**

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA S. MERCIER whose telephone number is

(571)272-9039. The examiner can normally be reached on 8:00am-4:30pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melissa S Mercier/
Examiner, Art Unit 1615

/Carlos A. Azpuru/
Primary Examiner, Art Unit 1615